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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/225,233	01/04/1999	KEITH HENRY STOCKMAN CAMPBELL	112800.401	2711

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Finnegan, Henderson, Farabow
Garrett & Dunner, L.L.p
1300 I Street, N.W.
Washington, DC 20005-3315

EXAMINER

CROUCH, DEBORAH

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 12/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/225,233

Applicant(s)

CAMPBELL ET AL.

Examiner

Deborah Crouch, Ph.D.

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 128 and 145 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 128 and 145 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 08/802,282.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1632

Applicant's arguments filed May 7, 2004 have been fully considered but they are not persuasive. The amendment has been entered. Pending claims are 128 and 145.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 128 and 145 remain rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 128 and 145, as written, do not sufficiently distinguish over nonhuman mammals, as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. Thus, the claims lack evidence of the hand-of-man. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). *See* MPEP 2105.

In particular, the claims are drawn to cloned nonhuman mammals produced by somatic cell nuclear transfer. However, the cloned mammals are not described, nor claimed, as having a new phenotype that would distinguish them from any previously existing or presently existing mammal of the same species.

Applicant argues that the claims are directed to an adult mammal and its "clone." A clone, applicant continues, requires asexual reproduction, and refers to American Heritage College Dictionary (third ed.). Applicant argues that nature does not make clones because mammals do not reproduce asexually in nature. Applicant argues that clones clearly have the hand of man because of the asexual reproduction aspect. These arguments are not persuasive.

The mammals claimed, while admittedly produced by new method, and that the method is asexual, the methods do not alter the mammals from its brethren in the wild or in

Art Unit: 1632

commerce. There is nothing different about the mammals that provide it with any distinctive quality, characteristic or use over those mammals produced sexually. A comparison would be the production of a calf by embryonic cell nuclear transfer. A calf so produced, as an example, has been produced by the hand of man but nothing about the calf is distinctive over other calves. A calf produced by ECNT would also be considered nonstatutory. This would be true even though the calf would not have a genotype of a prior existing bovine, as do the claimed clones. However, the fact that clones have the genotype of a prior existing bovine adds to the nonstatutory arguments. The claimed clones, as applicant argues later in their response, are replicas of a known mammal. If the mammals are copies of a previously known mammal that would have been considered nonstatutory, then the copy, the clone, of the mammal cannot be considered statutory. With the presently claimed clones, the ingenuity is with the method, and not the product.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 128 and 145 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nonprimate mammalian clone and a nonembryonic, nonprimate mammalian clone, does not reasonably provide enablement for nonhuman mammalian clones or nonembryonic, nonhuman mammalian clones. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

At the time of filing, the skilled artisan would have regarded the cloned primates as unpredictable.

Art Unit: 1632

Pennisi cites several scientists working in the area of mammalian cloning who point to a lack of general and reproducible success, thus, emphasizing the lack of predictability at the time of filing. Robert Wall of the USDA is quoted as stating that despite years of effort, "[w]e're in the same bind that we've always been in. A majority of [would be clones] do not make it to term." (Pennisi and Vogel (2000), page 1722, col. 1, parag. 2, lines 9-14).

Pennisi and Vogel state that "even when an embryo does successfully implant in the womb, pregnancies often end in miscarriages" (Pennisi and Vogel (2000), page 1722, col. 1, parag. 3, lines 16-18). As the authors state, establishing pregnancies is only part of the problem and is not a guarantee of a cloned mammal being produced (Pennisi and Vogel (2000), page 1726, col. 2, lines 9-11). Thus, at the time of filing, there appears to be such unpredictability that only the cloning of nonprimate mammals was predictable. With particular regards to primates two cloned monkeys were produced, but there have been no subsequent successes in primate cloning (Pennisi and Vogel (2000), page 1726, col. 2, line 6 to col. 3, line 3). In this regard, is a post-filing report in 2002 that the cloning of monkeys, a primate, by nuclear transfer had been successful when embryonic cells were the nuclear donor, not when somatic cells were used as nuclear donor (Mitalipov, abstract). Fourteen somatic cell NT embryos were transferred to 3 recipients (Mitalipov, page 1371, col. 1, parag. 1, lines 5-7). Mitalipov states that nuclear reprogramming is a limiting parameter in monkey somatic cell cloning (page 1371, col. 1, parag. 2, lines 13-25). Mitalipov further states, clearly, that somatic cell cloning has not been accomplished in primates (Mitalipov, page 1367, col. 2, parag. 3, lines 1-3). Thus, the art at the time of filing clearly indicates that full breadth of the claimed invention was not enabled. Thus, the skilled artisan would have needed to conduct an undue amount of experimentation without a predictable degree of success to implement the claimed invention for its entire breadth.

Art Unit: 1632

Claim 128 is and claim 145 remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 128 is to a nonhuman, adult mammal from which a somatic donor cell has been taken and clone of the adult mammal produced from the cell, where the clone is made by nuclear transfer methodology. Claim 145 is to a pair of non-human mammals comprising an adult, parental nonhuman mammal and its live offspring clone.

The subject matter of claims 128 and 145 lack written description as the specification never contemplates the nonhuman, adult mammal and its clone together nor does the specification contemplate a pair of non-human mammals comprising an adult, parental nonhuman mammal. The specification discloses nonhuman mammals as nuclear donors and nonhuman mammals as the clone of the donor, and contemplates them singularly. However, the specification never contemplates them either together or as a pair. There is no contemplation for the donor mammal to be living or that the cell is taken from the living donor for direct use in cloning (specification, page 7). The specification states that the donor cells can be, but don't have to be, cultured cells. This vague description does not provide support for cells taken directly from the donor mammal and inserted directly into the recipient enucleated oocyte. The specification also states that the donor cell can be an adult somatic cell, but there is no contemplation for an adult mammal that is the donor (specification, page 7, lines 16-20). The disclosure of an adult somatic cell as the donor cell is not seen as providing figurative support or literal support for "adult mammal." There is no support found for the term "parental."

Art Unit: 1632

To meet written description, the claimed invention must have been described in the specification as filed. *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

Applicant should point to page and line number where support for claims 128 and 145 can be found.

With regard to claim 145, applicant argues the specification need not disclose the invention in identical words, but that they only need to allow the skilled artisan to recognize that applicant's invented what is claimed. Applicant argues that "clone" implies that a mammal is a copy of some other mammal, the donor, and thus the term conveys the concept of a pair of animals, the donor and the clone. Applicant argues that this concept exists when the clone is born and that the skilled artisan would recognize this. Applicant argues that the disclosure of a clone and its parental (donor) mammal, together with the fundamental relationship between them, is sufficient to convey possession of claims 145 at the time of filing. These arguments are not persuasive.

While figurative support can supply support for terminology in amendments to claims, in the present case, such figurative support cannot be found. There are not any instances in the specification where contemplation of the parent and clone are seen together. While the donor is contemplated and the clone is contemplated, there is not any contemplation of the together. The skilled artisan would recognize possession of each separately at the time of filing, but there is no evidence to support the skilled artisan recognizing them together.

Art Unit: 1632

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 145 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 145 contains the term "adult," but the specification does not clearly define the term. Does this refer to any term animal, an animal that has reached sexual maturity or some other post-birth stage of life.

Claim 145 also contains the term "parental." However, the specification does not define "parental." In instances of nuclear transfer, the parent could be either the donor or the surrogate mother. This confusion is noteworthy as the surrogate mother supplies functions of parents: birthing, feeding, grooming and teaching.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 145 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Sims et al. (1993) Proceed. Natl. Acad. Sci. 90, 6143-6147.

Sims teaches a parental heifer and her live offspring clone (page 6146, col. 1, parag. 2, lines 6-11). The heifer gave birth to a clone of a bovine embryo. Thus, the clone is her offspring. Sims meets each limitation of the claim. Therefore, Sims clearly anticipates the claimed invention.

Art Unit: 1632

Applicant should note that claim 145 does not require that the clone be a clone of the parent.

Claims 128 and 145 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Seike et al. (1991) J. Vet. Med. Sci. 53, pp. 37-42.

Seike teaches the production of calves by demi embryos. The demi-embryos were split. One demi-embryo was transferred to a surrogate mother for development into a calf. The second demi-embryo was frozen for 43 days, thawed and transferred to a heifer for development into a calf. The result was identical twin calves 79 days apart in age. See page 38, col. 2, parag. 1 to page 39, col. 2, line 12, and table 3. As the calves of Seike produced from demi-embryos could not be distinguished from the donor and clone or parent and clone presently claimed, respectively in claims 128 and 145. Thus, Seike clearly anticipates the claimed invention.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 128 and 145 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Morris et al (1993) J. Reproduc. Fertil. 97, 255-261.

Morris teaches a heifer that gave birth to twin calves (page 259, col. 1, parag. 1). Thus, the heifer and either of the twin calves anticipate, respectively, the nonhuman adult mammal from which a somatic cell has been taken and clone of the adult mammal (claim 128). Additionally, the heifer and either of the twin calves anticipate a pair of nonhuman

Art Unit: 1632

mammals comprising an adult, parental nonhuman mammal and its offspring produced by cloning (claim 145).

In the alternative the heifer and twin calves taught by Morris render the claimed nonhuman adult mammal and its clone (claim 128) and the claimed pair of nonhuman mammals (claim 145) obvious because there is no disclosed or discernable patentable distinction between Morris heifer and calves, and the mammals claimed. Applicant argues that claims 128 and 145 require a "clone" of the adult mammal. Applicant argues that the heifer was mated, and thus the offspring cannot possibly be a clone because half of the calf's chromosomes are from each parent. Applicant argues that because the claimed "clone" received all of its chromosomes from a single parent, the clone is distinguished from the calf of Morris. Applicant argues that the term "clone" serves as a structural limitation that distinguishes the claimed mammals from those of the prior art. Applicant argues that unlike the heifer and calves of Morris, the claimed clone has the same set of chromosomes as the claimed parental mammal. Applicant argues that having the same set of chromosomes is an unexpected property of applicant's claimed methods. These arguments are not persuasive.

It is not clear what applicant means by the same set of chromosomes. Does applicant mean the same chromosomes that were in the donor, chromosomes that have identical nucleotide sequence, chromosomes that have the same karyotype or a group of chromosomes having the same number as the pre-existing mammal? Obviously, the clone cannot have the same identical set of chromosomes as found in the donor. The clone and the donor are unlikely to have the same identical nucleotide sequence because during DNA replication there more likely than not will be some nucleotide changes at least in the "junk" DNA regions or introns, if not some silent mutations in coding regions. Additionally, there is no evidence of record that the donor and clone of claims 128 and 145 have genomes that

Art Unit: 1632

are nucleotide sequence identical. The donor and clone will have the same karyotype or chromosomal number. It is noted that the donor and clone chromosomes comprised of genes encoding the same proteins. Thus, based on genome alone, the heifer and calves of Morris, and the claimed donor and clone or parent and clone, cannot be distinguished. Applicant has not pointed to any distinguishing feature such as a protein expression level, ear shape or other physical manifestation that would indicate a genotypic difference between the heifer and calves of Morris and the mammals of claims 128 and 145. If the bovines of Morris and bovines encompassed by claims 128 and 145 are side-by-side, there is no feature that would distinguish them either in a direct comparison or in an indirect comparison of features.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Reynolds, SPE of AU 1632 whose telephone number 703-305-4051. The examiner can normally be reached on M-Th.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.



Deborah Crouch, Ph.D.
Primary Examiner
Art Unit 1632

December 22, 2004